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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,836	08/19/2003	Jean-Baptiste Dumas Milne Edwards	G-078US05DIV	4906

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,836	DUMAS MILNE EDWARDS ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/24/04;7/6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Informalities

The disclosure is objected to because of the following informalities:

1. The specification (e.g., page 45, line 4; page 68, lines 29, 32 and 33; page 435, line 2) recites embedded hyperlinks and/or other forms of browser-executable code, which are impermissible and require deletion. Appropriate correction is required.

2. The specification recites SEQ ID NO:297 is identical to synaptogyrin 1 up to and including amino acid "122" (page 280, line 28). However, the sequence alignment of the two peptides (see attached sequence alignment) indicates the two sequences are identical up to residue 112, not 122. Appropriate clarification is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-16 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. The claims are directed to an isolated polypeptide comprising an amino acid sequence at least 90%, 95%, 96%, 97%, 98% or 99% identical to the amino acid sequence of SEQ ID NO:297 or a composition comprising the polypeptide. The polypeptide of SEQ ID NO:297 is disclosed as a splice variant of synaptogyrin 1 and is identical to synaptogyrin 1 up to amino acid residue 112 (see attached sequence alignment), where the protein of SEQ ID NO:297 has the same N-terminal domain and 2 of 4 transmembrane helices. The specification discloses the preferred

polypeptides of the invention are those that comprise the N-terminal cytoplasmic domain (residues 1-16) of the protein, which are highly conserved among all the members of synaptogyrin family (Fig. 6 of Kedra et al., Human Genetics 103, 131-141 (1998)); and that comprise amino acids 25-45 and/or 68-88, which are the two transmembrane alpha helices, thus it is believed the protein of the invention is a member of the synaptogyrin family (page 280, line 21 to page 281, line 2 of the specification). The specification also indicates that synaptogyrins are closely related to proteins of the synaptophysin family, both of which are involved in neurotransmission and more generally exocytosis and vesicle trafficking (page 281, lines 3-11), and the normal function and organization of eukaryotic cells is dependent on the transport of various vesicles that selectively shuttle membrane and cargo between distinct compartments of the secretory and endocytotic pathways, where numerous human diseases can be attributed to defects in the trafficking of proteins to organelles or the cell surfaces (page 281, line 12- page 282, line 14). Thus, the protein of the invention can be used in to diagnose, treat, and prevent any disorder in which trafficking or the fusion machinery is affected (pages 282-284). The comparison of SEQ ID NO:297 (132 amino acids) with synaptogyrin 1 (234 amino acids) indicates the protein of SEQ ID NO:297 has the same N-terminal domain and 2 of 4 transmembrane helices (see attached sequence alignment), which appears to be the basis of that SEQ ID NO:297 or its related protein being identified as a member of synaptogyrin family. However, the members of synaptogyrin family have central portions of the proteins (residues 34-161) strongly conserved and four membrane-spanning helices (Fig. 6, and pages 137-138 of Kedra et al., 1998), while the protein of SEQ ID NO:297 only contains a portion of the synaptogyrin protein. Thus, it is not known whether SEQ ID NO:297 or it related proteins has

the biological activity in vesicle trafficking as members of synaptogyrin family without further experimentation. Since SEQ ID NO:297 as being a functional synaptogyrin protein have not been demonstrated in the specification, thus, its functional role is not established. For these reasons, the instant invention does not possess a specific or a well-established utility, although there is a general utility that is applicable to the broad class of synaptogyrin proteins. The utility is not a substantial utility because it requires further research to identify or reasonably confirm a "real world" context of use. Basic research to characterize the claimed invention, use in an assay to identify modulators of the instant invention, or production of antibodies to identify other related proteins do not constitute substantial utilities.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-16 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

5. Claims 1-5, 7, 9-13 and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-3, 5, 7, 9-11, 13 and 15 are directed to an isolated polypeptide comprising an amino acid sequence at least 90%, 95%, 96%, 97%, 98% or 99% identical to the amino acid sequence of SEQ ID NO:297, where the polypeptide may play a role in vesicle trafficking. The specification discloses the protein of SEQ ID NO:297 is a splice variant of synaptogyrin 1 and is identical to synaptogyrin 1 up to amino acid residue 112, where the protein of SEQ ID NO:297 has the same N-terminal domain and 2 of 4 transmembrane helixes; and synnaptogyrins are closely related to proteins of the synaptophysin family, both of which are involved in neurotransmission and more generally exocytosis and vesicle trafficking (see attached sequence alignment; page 280, line 21-topage 281, line 11 of the specification). However, there is no disclosure of any particular structure to function/activity relationship in the disclosed species (i.e., polypeptides comprising amino acid sequences at least 90% identical to SEQ ID NO:297). Without guidance for structure to function/activity of the claimed polypeptides, one skilled in the art would not know which portions or fragments of the sequence are essential for function/activity, and how to produce a functional polypeptide. The lack of description on the structure to function/activity relationship of the polypeptides, and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

6. Claims 3 and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ pool of cells containing specific clones (e.g., 181-3-3-0-C9-CS) to obtain specific protein products. The written description of those cells and the method of isolating are insufficiently reproducible. Therefore, a deposit for patent purposes is required. The specification discloses at page 28 that cells containing the sequences of SEQ ID NOs:1-241 was deposited with the American Tissue Culture Collection (ATCC) at Manassas, VA, USA on January 21, 2000.

For compliance with the rule, it must be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent. MPEP 2403.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

While the instant specification contains deposit information, the requirements to enable such a deposit have not been fully met by the instant application because the record must also contain a statement certifying that all restrictions on accessibility to said deposit be irrevocably removed by Applicant upon the granting of the patent (see M.P.E.P. § 2404.01); this statement may be certified by Applicants or Applicants' representative.

Conclusion

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CMK
November 10, 2005